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Datasheet for the decision of 22 January 2019

Case Number: T 2699/17 - 3.2.08
Application Number: 05101327.4
Publication Number: 1693022
IPC: A61C9/00

Language of the proceedings: EN

Title of invention:
A cap for use in a process for the retraction of sulcus

Applicant:
Coltène/Whaledent AG

Headword:

Relevant legal provisions:
EPC Art. 53(c), 111(1)

Keyword:
Exceptions to patentability - method for treatment by surgery - (no)
Reimbursement of appeal fee - substantial procedural violation (no)
Appeal decision - remittal to the department of first instance (yes)
Decisions cited:
G 0001/07, T 2707/16, T 1695/07, T 0663/02

Catchword:
DECISION of Technical Board of Appeal 3.2.08 of 22 January 2019

Appellant: Coltène/Whaledent AG
(Feldwiesenstrasse 20
9450 Altstaetten (CH))

Representative: Hepp Wenger Ryffel AG
(Friedtalweg 5
9500 Wil (CH))

Decision under appeal: Decision of the Examining Division of the European Patent Office posted on 20 September 2017 refusing European patent application No. 05101327.4 pursuant to Article 97(2) EPC.

Composition of the Board: Chairwoman P. Acton
Members: C. Herberhold
C. Schmidt
Summary of Facts and Submissions

I. By decision posted on 20 September 2017 the examining division refused European patent application No. 05 101 327.4.

II. In its decision, the examining division held that claim 1 of the main request defined a method for treatment of the human or animal body by surgery in respect of which a patent shall not be granted according to Article 53(c) EPC.

III. The appellant (applicant) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.

IV. Oral proceedings before the Board were held on 22 January 2019.

At the end of the oral proceedings, the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or on the basis of the 1st auxiliary request, both filed with the letter setting out the grounds of appeal dated 23 October 2017.

It further requested non-remittal of the case to the examining division and reimbursement of the appeal fee.

V. The independent process claims of the main request read as follows:

Claim 1:
"A process of retraction of sulcus (3), comprising the steps of:

..."
i. applying an elastomeric material, preferably a silicone material (4), a polyurethane material and/or a polyether material onto and/or at the vicinity of the boundary of a tooth (1) and adjacent gingiva (2) and/or sulcus (3), which elastomeric material (4) expands during or after its curing reaction;

ii. applying a cap (6) onto said tooth (1), thereby forming a chamber over said elastomeric material (4), wherein said chamber comprises as its walls the tooth (1), the cap (6) and an outer section (2a) of said gingiva (2);

whereby said chamber allows for the elastomeric material (4) to expand into the sulcus (3), characterized in that

- said cap (6) is at least partially filled with a plastically deformable, especially malleable material (7) when applied onto said tooth (1) in step ii.;

and/or that

said cap (6) is deformable, especially under biting pressure."

Claim 2:
"A process of retraction of sulcus (3), comprising the steps of:

i. at least partially filling an elastomeric material, preferably a silicone material (4), a polyurethane material and/or a polyether material into a cap (6) which elastomeric material (4) expands during or after its curing reaction;
ii. applying said cap (6) onto a tooth (1), thereby forming a chamber for said elastomeric material (4), wherein said chamber comprises as its walls the tooth (1), the cap (6) and an outer section (2a) of said gingiva (2);

whereby said chamber allows for the elastomeric material (4) to expand into the sulcus (3), and wherein said cap (6) is deformable, especially under biting pressure."

VI. The device claims of the main request and the auxiliary request have no bearing on the present decision.

VII. The following documents played a role in the present decision:


A2.1: "Stellungnahme zur klinischen Anwendung und Produktssicherheit von Magic Foam Cord"; Dumfahrt, H. and Steinmassl, P;


A5: Product flyer "roeko", Cotton products, Coltène / Whaledent 06/16.

VIII. The essential arguments of the appellant can be summarised as follows:

Article 53(c)

The appellant fully agreed with the Board's communication dated 14 September 2018 in that the health risks involved by the claimed method did not qualify as substantial within the meaning of G1/07.

However, in so far as the Board in its communication followed the approach of decision T 1695/07, the appellant had serious concerns, in particular with respect to the statement in point 12.2.2 of the reasons according to which the evaluation of the health risk implied a consideration of the physical state of the individual patient and a judgement of the health risks in relation to the potential benefit to be achieved by the intervention. Indeed, by malicious choice of a particular individual patient, a considerable health risk could be provoked for basically every method. Even piercing, mentioned in G 1/07 as involving a non-substantial health risk, could have serious
consequences when applied in a severely compromised infected skin area, a procedure which nobody would perform. In the appellant’s view, an objective risk evaluation using the risk matrix approach developed in T 663/02 was to be preferred.

**Substantial procedural violation - reimbursement of the appeal fee**

The proceedings before the examining division were tainted by several substantial procedural violations.

Firstly, the overall case duration of more than 12 years between filing and refusal was excessive. As discussed in detail in recent decision T 2707/16, delays which, taken alone, are acceptable may still result in an unacceptable overall delay. This applied precisely to the situation in the present case. However, contrary to case T 2707/16 in which the applicant had remained inactive for several years, in the present case the appellant had reacted rapidly and thoroughly to all communications from the examining division. While it was true that no PACE request had been filed, such a long duration was untenable for a "normal", i.e. non-accelerated, case too. Even the issuance of decision G 1/07 could not justify such a long duration. Thus, a substantial procedural violation should be acknowledged.

Secondly, during the proceedings the examining division had acted inconsistently. Initially, "bleeding" was held as indicating a substantial health risk. In a letter from the EPO, it was then acknowledged that whether or not bleeding occurred was irrelevant. Nevertheless, later in the proceedings, e.g. in the summons and in the decision, the alleged occurrence of
bleeding in the process re-surfaced as a decisive argument. Likewise, in one letter of the examining division the Article 53(c) objection was withdrawn, whereas in the next office action — the summons to oral proceedings — it was again raised, after "thorough examination by all 3 members of the examining division". This "see-saw" reasoning was against the Guidelines C-VIII, 1, which clearly stated that the primary examiner was always acting on behalf of the examining division and that the applicant was entitled to assume that if the examiner had doubts as to the views of the rest of the division he would have discussed the matter with them beforehand. This workflow had obviously not been respected in the present case, which resulted in a substantial procedural violation.

Thirdly, in its decision, the examining division had simply repeated its allegations from the summons, without taking into account any of the detailed counterarguments discussed in the scientific papers or in the expert evidence provided in preparation for the hearing. In particular, one of the apparently decisive arguments, the argument based on the alleged occurrence of bleeding, had been clearly proven wrong in said submissions, without the examining division reacting in any way to the arguments brought forward. Likewise, all other arguments brought forward by the examining division had been rebutted in the appellant's submission. The decision took no account of this reasoning and was thus not properly substantiated.

Even worse, another apparently decisive argument of the decision, according to which it was not proven by the appellant that the statements and information provided pertained to the subject-matter of claim 1, had made
its first appearance in the impugned decision without having been discussed in the oral proceedings, and without the appellant having the opportunity to present its comments in this respect. Consequently, the appellant's right to be heard had been violated.

All these substantial procedural violations justified a reimbursement of the appeal fee.

No remittal to the department of first instance.

In view of all the deficiencies in the first instance proceedings, the appellant had lost trust in the examining division, such that it asked that the case not be remitted.

Reasons for the Decision

1. Article 53(c)

1.1 According to Article 53(c) EPC, European patents "shall not be granted in respect of ... methods for treatment of the human or animal body by surgery ... ".

The criteria of decision G 1/07 (OJ EPO 2011, 134)

Following decision G 1/07, the methods excluded from patentability pursuant to Article 53(c) EPC as methods for treatment of the human or animal body by surgery are methods in which maintaining the life and health of the subject is important and which comprise or encompass an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when


carried out with the required professional care and expertise.

As summarised in T 1695/07, point 6.3 of the reasons, G 1/07 advocates for a "narrower understanding" of what constitutes by its nature a "treatment by surgery" within the meaning of Article 53(c) EPC, which ruled out from the scope of the application of the exclusion clause "uncritical methods involving only a minor intervention and no substantial health risks, when carried out with the required care and skill, while still adequately protecting the medical profession". In particular, G 1/07 found that it "appeared hardly still justified to exclude from patentability certain, albeit invasive techniques, at least when performed on uncritical parts of the body", which were carried out in a non-medical, commercial environment like in cosmetic salons and in beauty parlours". This was said to apply "as a rule to treatments such as tattooing, piercing, hair removal by optical radiation, micro abrasion of the skin".

On the other hand, the "definition of the term "treatment by surgery" must cover the kind of interventions which represent the core of the medical profession's activities, i.e. the kind of interventions for which their members are specifically trained and for which they assume a particular responsibility". These physical interventions on the body were defined as those which "require professional medical skills to be carried out and which involve health risks even when carried out with the required medical professional care and expertise".
In the following, these criteria defined in G 1/07 are applied to the specific method claimed.

**The invention**

1.2 The present application relates to the guided expansion of an elastomeric material within the sulcus of a tooth. In this way, the gingiva is retracted from the tooth, such that an appropriate impression of the tooth may be obtained, which is then used in the manufacture of the crown restoration.

1.3 Anatomically, the gingival sulcus lies between the enamel of the tooth and the gingiva. On the gingival side, the surface is covered by the sulcular epithelium (which sits on a basal membrane). The sulcus forms a "pocket" (such pockets markedly increase in size in periodontal disease). At its bottom, the epithelium comes into contact with the cementum (junctional epithelium), even further caudal, the gingival/periodontal fibres anchor the tooth root to the bone and the gingiva.

**The health risk involved**

1.4 Sulcus retraction widens the sulcus by different techniques, some of which (mechanochemical = insertion of impregnated cord, purely mechanical, electrosurgical) have been associated with necrosis and/or stripping of the gingival sulcus, permanent periodontal damage and even bone loss (see e.g. document A.2.4, Introduction, page 2, 3rd para). Necrosis, permanent periodontal damage and bone loss would appear to qualify as substantial health risks.
1.5 However, with regard to sulcus retraction by so-called "retraction pastes", the evidence provided by the appellant points to a considerably minor health risk. This is true, in particular, for "Magic Foam Cord", which is an expanding polyvinyl siloxane material (see document A2.5, page 1054, left-hand column, "cordless techniques", line 27 ff), i.e. a material falling under the definition of claim 1.

Document A2.5 reports on a study in which healthy subjects were tested (see Material and Methods, first paragraph). For Magic Foam Cord, the probing depth (measured essentially by carefully inserting a probe into the pockets) remained almost the same at baseline, 1 and 7 days respectively (see Table 3 and "results, page 1056, left-hand column, lines 6-9). This indicates that the periodontal attachment fibres were not violated. The gingival index (an index for gingiva irritation and inflammation) increased after the retraction, but after seven days decreased to a non-significant level compared with the baseline measurements (Table 3, page 1056, the passage bridging the middle and right columns). No bleeding occurred with the cordless techniques (page 1056, right-hand column, second paragraph).

1.6 The study underlying document A2.4 investigated the effect of retraction material on gingival health using histopathological means (in this case the subject did not have healthy teeth but teeth which needed to be extracted, although still without periodontal disease; see "Conclusion, Future research"). Magic Foam Cord was found to respect the periodontium (Abstract, "Conclusion", last sentence). In most cases, even the junctional epithelium was found to remain intact ("Discussion", penultimate paragraph).
1.7 These clinical findings are in accordance with Magic Foam Paste exhibiting only a mild pressure of 32.8 kPa (document A2.3, Abstract, Results), which is far below the 2 400 kPa found by Van der Velden to allow a probe tip to reach the bottom of the sulcus while maintaining an intact coronal connective tissue (A2.3, page 164, left-hand column, lines 2-9; see also Van der Velden's study A2.2).

1.8 The clinical/scientific evidence provided thus supports the statement by Mr Dumfahrt and Mrs Steinmassl (A2.1, last paragraph), according to which Magic Foam Cord is a gentle gingival retraction means which does not disrupt the gingival basal membrane.

1.9 To conclude, the periodontal connective tissue remains intact and minor injury of the epithelium may occur, which may also lead to bleeding (in particular with inflamed or pre-damaged tissue). If the epithelium is damaged, bacteria may invade, thereby causing inflammation. However, both bleeding and inflammation were found to rapidly heal.

1.10 While the evidence provided applies to a particular paste (Magic Foam Cord), in view of the pressure determined by Van der Velden (A2.2) and the pressures measured in (A2.3) there is a broad "safety margin", such that extrapolation of the experimental data to the other pastes falling under the claim is justified.

*Does the method qualify as "substantial physical intervention on the body", i.e. is the health risk a substantial health risk within the meaning of G 1/07?*
1.11 After establishing the health risk involved, it has to be decided whether that health risk qualifies as substantial within the meaning of G 1/07, i.e. whether the risk goes beyond the side effects of piercing, hair removal by optical radiation, or microabrasion of the skin.

For that evaluation, different approaches have been suggested in case law, namely, the 'risk matrix' in decision T 663/02 and a 'more abstract risk criterion' in decision T 1695/07 (see point 12.2.4 of the reasons).

In the present decision essentially, the 'more abstract risk criterion' approach is followed, which in the view of the present Board provides for a practical and feasible assessment of the health risk involved.

As to the appellant's concerns regarding T 1695/07 allegedly advocating - according to point 12.2.2 of its reasons - an evaluation of the individual health risk of the individual patient and judging the health risk in relation to the potential benefit to be achieved by the intervention, the Board notes the following: In decision T 1695/07, point 12.2 of the reasons explains why Board 3.3.07 considers that G 1/07 cannot be understood as requiring a factual risk analysis based on objective evidence, such as performed in T 663/02 ("risk matrix"). Its arguments in this respect are discussed in points 12.2.1 and 12.2.2 of the reasons (i.e. in the passage the appellant is concerned about). Point 12.2.1 essentially states that already for an "absolute scale" risk analysis, significant and reliable data are not normally available. As discussed in point 12.2.2, the situation is even worse with respect to the relative risk of a specific patient,
i.e. when trying to draw up an individualised risk matrix for the particular patient concerned. From these arguments the Board then concludes (point 12.2.3 of the reasons) that "an objective and concrete analysis of the absolute or relative risks, which is hardly feasible, cannot have been intended by the Enlarged Board of Appeal and should therefore not be required".

Indeed, T 1695/07 does not advocate the analysis of a relative risk. The appellant's concerns in this respect are unfounded. Instead, see T 1695/07, point 12.2.4 of the reasons, the assessment should be limited to a more abstract basis, i.e. to the question "Is a certain health risk present?" and "Is it substantial?".

The present Board joins the concerns of Board 3.3.07 with respect to the practical feasibility of the "risk matrix" approach of T 663/02, which consequently is not applied to the present case.

With respect to the appellant's argument that by a malicious choice of the patient, a considerable (individual) health risk could be provoked for basically every method, the following is noted: G 1/07 talks about a "substantial health risk even when carried out with the required professional care and expertise". This wording excludes considering as substantial those health risks which only occur in patients for which the method in question is clearly contraindicated, such that their execution on the respective patient would have to be seen as going against the required professional care and expertise.

1.12 Superficial bleeding and superficial germ invasion are typical risks associated with procedures such as piercing or microabrasion of the skin. Such bleeding
can usually be easily controlled (either it stops spontaneously or by simple application of external pressure). Likewise, the superficial infection is usually overcome by the body's immune system.

The Board is of the opinion that the risks established above (see point 1.8) for the claimed method are at a level with those present in methods which G 1/07 considered not to involve a substantial health risk.

Thus, the claimed method does not comprise or encompass an invasive step representing a substantial physical intervention on the body and does not entail a substantial health risk in the sense of G 1/07.

Criticality of the body part

1.13 Furthermore, with the deeper tissue, i.e. the periodontal connective tissue, remaining intact (see point 1.9 above), and the possible damage being limited to the superficial epithelium, the claimed method qualifies as a method of a low degree of intervention being applied to uncritical parts of the body in the sense of G 1/07.

Medical expertise/specific training required?

1.14 The cap is held in place by the patient's counter bite, with the retraction being essentially self-regulated through the pressure developed in the curing material. Moreover, during curing the actual degree of sulcus retraction cannot be judged because the site is covered by the cup and the retraction paste.

Thus, the specific training necessary for performing the method is minimal, as is the medical expertise
required from the person applying the method. With the process being essentially self-regulated, the person performing the method, furthermore, does not assume a particular responsibility therefore.

*Intervention representing the core of the medical profession's activity*

1.15 Moreover, sulcus retraction is one step in the preparation of an impression which is subsequently used e.g. for the manufacture of a dental crown. In other words, it belongs to the context of manufacturing a dental implant and is thus not at the core of the dental practitioner's freedom to choose the best treatment for the patient, which is rather in deciding that the patient needs a crown, to prepare the tooth accordingly, and to apply the crown. There is thus no need to exclude the claimed method to guarantee the freedom of the medical profession to apply the treatment of choice.

1.16 In conclusion, the Board is of the opinion that the method according to claims 1 and 2 does not fall under the exception defined in Article 53(c) EPC.

2. Alleged substantial procedural violation

2.1 Duration of the proceedings

The application was filed in February 2005 and the decision to refuse the application was issued in September 2017, which amounts to a total processing time of more than 12 years. The Board agrees that this is by far above the average duration of an examination procedure.
In decision T 2707/16 (cited by the appellant) Board 3.5.07 held that an excessive duration of proceedings may amount to a substantial procedural violation. Without entering in the discussion whether this view is fundamentally correct (see in this respect the discussion under point 17 of the reasons), T2707/16 states under points 29 and 30, that the reasonableness of the length of the proceedings must be assessed in each case according to the particular circumstances, taking into account among others the factual, procedural and legal complexity of the case.

As also conceded by the appellant, in the present case there was no single unacceptably excessive delay, such as the long period of stagnation in case T2707/16. Instead, the examining division regularly returned to the case and addressed various issues of substance, which the appellant promptly addressed.

Furthermore, during the prosecution of the case, Enlarged Board of Appeal decision G1/07 was issued which was highly pertinent particularly with respect to the objection under Article 53(c) EPC. The Board is of the opinion that taking into account said decision and in particular the case law which only evolved in the years after its issuance explains and justifies to some extent the delays in the present case (and possibly the division's "see-saw reasoning"/"change of mind" which the appellant complains about; see below).

Moreover, the Office offers appellants the opportunity via the so-called PACE programme (see e.g. the Guidelines E-VIII, 4) to accelerate the proceedings. By decision of the President dated 12 July 2007 (Special edition No. 3, OJ EPO 2007, J.3), such requests are not published and are excluded from file inspection.
The Board cannot see why the appellant, who apparently was aware of but not satisfied with (in its view) the too slow but regular pace of the proceedings, waited until the appeal stage to voice its concerns instead of making use of the PACE programme, which gives applicants a convenient tool to speed up the pace at which the proceedings are progressing.

To conclude, taking into account the particular circumstances of the case, the Board comes to the conclusion that although undesirably long, the duration of the case does not amount to a substantial procedural violation.

2.2 "See-saw" reasoning

The messages that the appellant received from the EPO in this case were uncontestedly inconsistent.

However, the statement that bleeding was of no relevance originated from a person who was never part of the examining division. For that reason alone, the fact that this statement was not followed later on cannot result in a procedural error by the division.

With respect to the communication dated 22 August 2014 in which the Article 53(c) EPC objection was withdrawn, the appellant was of the opinion that the first examiner had obviously acted contrary to the Guidelines for Examination C-VIII, 1, 3rd paragraph, and had not discussed the case with the other members of the division. This could be derived from the introductory sentence of point 3.1 of the subsequent summons, which explained the change of mind to be the result of
"thorough examination by all 3 members of the examining division". This objection is, however, purely speculative. Whether the change of mind was caused by the two other members of the division having their first say in the case or rather by a change of mind of the whole division cannot be established. In this context, the Board notes that points III.c and III.d of the decision point to an involvement of the whole division, which was initially "convinced ... that the method claims previously objected to were allowable ..." (point III.c) but then "re-evaluated all arguments on file and came to the conclusion that present method claims 1-11 and 18-21 did not fulfil the requirements of Article 53(c) EPC..." (point III.d). A change of mind - although surprising and in this case negative for the appellant - is neither forbidden by the EPC nor is it a substantial procedural violation.

2.3 Alleged violation of the right to be heard

In the summons, the examining division argued that the method could result in bleeding of the affected tissue (point 3.1.1). Due to bleeding, germs could enter the blood vessels, which was considered a substantial health risk (point 3.1.3). As these arguments were part of the summons, the appellant was aware of that reasoning and had the opportunity to present its comments in the oral proceedings. The decision is - at least in part - again based on this line of argument (see point 1 of the decision for the bleeding argument and point 3 for the health risk entailed therewith). Furthermore, the argument cannot be considered a pure allegation. The division made explicit reference to paragraphs [0021] and [0027] of the application as filed, which mention the possible use of a haemostatic compound, which is indeed a very strong indication that
bleeding may occur - even though annexes 1 and 2 argue against it.

Bleeding implies the possibility of germs entering the blood vessels. This has not been denied by the appellant. Germs entering the blood vessels can cause infections and thus entail a certain health risk. If that health risk were substantial, a refusal of the method under Article 53(c) EPC in accordance with G 1/07 would be justified. There is thus at least one complete line of argument of which the appellant was aware and on which it could present its comments.

Whether this health risk is substantial or not is a question of judgement. The present Board agrees with the appellant (see point 1 above) that the health risk is indeed minor and not "substantial" in the sense of G 1/07. The examining division's decision thus suffers from an "error in judgement". Such errors in judgement do not constitute, however, a substantial procedural violation.

The decision further takes the appellant's submissions and arguments into account in that it argues (reasons, point 1, penultimate paragraph) - referring to decision T 5/04 - that even if the method were atraumatic (as advocated in annexes 1 and 2), a surgical method could be present. While these arguments appear not to be satisfactory, let alone convincing to the appellant, they still show that the division did indeed react to the submissions.

The appellant has argued that it only became aware of the division's argument, according to which it was not proven by the appellant that the statements and information provided in annexes 1 and 2 pertained to
the subject-matter of claim 1, in the decision and thus could not present its comments. As pointed out in the summons, the Board has no way of ascertaining whether this argument was indeed not discussed during the oral proceedings. However, in view of the reasoning discussed above regarding bleeding and the health risk involved therewith, any procedural violation with respect to a further argument or line of argument would not have changed the result of the examination proceedings, the application having been refused already for the first reason. A potential procedural violation which is not causal to the decision cannot be considered substantial.

Therefore, the Board comes to the conclusion that there was no substantial procedural violation present.

2.4 No reimbursement of the appeal fee.

Without a substantial procedural violation there is no reason to reimburse the appeal fee.

3. Remittal to the department of first instance

The present decision exclusively dealt with objections under Article 53(c) EPC. The examining division had, however, already discussed with the appellant the other requirements of the EPC, in particular novelty and inventive step. Indeed, a rule 71(3) EPC communication was issued with respect to an auxiliary request only comprising the device claims. It is thus reasonable to remit the case to a division which is already familiar with the issues that remain to be discussed.

The Board further notes that although some unfortunate events have aggregated in the present case, there is no
sign of the division being in any way biased or prejudiced against the appellant.

The case is thus remitted to the examining division for further prosecution in accordance with Article 111(1) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution.

3. The request for reimbursement of the appeal-fee is rejected.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated